

Remarks

In the outstanding Official Action, the Examiner:

(1) objected to the disclosure and requested an update of the status of the applications which Applicant is claiming priority to in the first paragraph of the specification, and required appropriate correction;

(2) rejected claim 5 under 35 USC 112, second paragraph, as failing to particularly point out and distinctly claim the subject matter which Applicant regards as the invention;

(3) rejected claim 5 under 35 USC 102(e) as being anticipated by Adams; and

(4) rejected claim 5 under 35 USC 102(b) as being anticipated by Sugiyama et al.

In response to Item 1 above, Applicant has now amended the first paragraph of the specification so as to update the status of the applications identified therein. Accordingly, the specification is believed to be allowable.

In response to Item 2 above, Applicant has now amended claim 5 to more clearly define the present invention. Specifically, Applicant has now amended claim 5 to define the thread pitch as "not greater than the circumference of an imaginary circle inscribing the outer boundary of said thread". Accordingly, the rejection of claim 5 under 35 USC 112, second paragraph, is believed to have been rendered moot.

In response to Item 3 above, Applicant respectfully traverses the rejection of claim 5 under 35 USC 102(e) as being anticipated by Adams. Claim 5 of the present invention comprises a threaded dilator for dilating mammalian

genitourinary and gastrointestinal passages, the dilator comprising a flexible shaft incorporating a tapered bulb near it's distal end with a helical thread of uniform pitch disposed thereon, the thread having a thread height of at least one fifth (1/5) of the outside diameter of the shaft and a thread pitch not greater than the circumference of an imaginary circle enscribing the outer boundary of the thread.

Applicant believes that Adams discloses a catheter having a balloon and a wrap located around the balloon to maintain the desired shape during inflation. Applicant has carefully reviewed Adams and believes that Adams does not disclose a threaded dilator having either one of (1) a tapered bulb with a helical thread, or (2) a helical thread having a height of at least one fifth (1/5) of the outside diameter of the shaft. Applicant believes that the wrap around the balloon is not a helical thread inasmuch as it is neither helical nor a thread, and that the wrap around the balloon does not have a height of at least one fifth (1/5) of the outside diameter of the balloon. Accordingly, claim 5 is believed to be in condition for allowance, and allowance thereof is respectfully requested.

In response to Item 4 above, Applicant respectfully transverses the rejection of claim 5 under USC 102(b) as being anticipated by Sugiyama et al. Claim 5 of the present invention comprises a threaded dilator for dilating mammalian genitourinary and gastrointestinal passages, the dilator comprising a flexible shaft incorporating a tapered bulb near it's distal end with a helical thread of uniform pitch disposed thereon, the thread having a thread height of at least one fifth

(1/5) of the outside diameter of the shaft and a thread pitch not greater than the circumference of an imaginary circle inscribing the outer boundary of said thread.

Applicant believes that Sugiyama et al. discloses a balloon catheter including a tubular body with a lumen in the tubular body and a reinforcement coil provided on the outer surface of the tubular body surrounded by a balloon. Applicant has carefully reviewed Sugiyama et al. and believes that Sugiyama et al. do not disclose a threaded dilator having either one of (1) a tapered bulb with a helical thread, or (2) a helical thread having a height of at least one fifth (1/5) of the outside diameter of the shaft. Applicant believes that the reinforcement coil disposed on the shaft within the balloon is not a helical thread inasmuch as it is not a thread and does not have a thread pitch, and that the reinforcement coil disposed within the balloon does not have a height of at least one fifth (1/5) of the outside diameter of the shaft. Accordingly, claim 5 is believed to be in condition for allowance, and allowance thereof is respectfully requested.

In the event that any fees may be required in this matter,  
please charge the same to Deposit Account No. 16-0221.

Thank you.

Respectfully submitted,

*James A. Sheridan* 3/15/04  
James A. Sheridan

Registration No. 43,114

Pandiscio & Pandiscio

470 Totten Pond Road

Waltham, MA 02451-1914

Tel. (781) 290-0060

KK/FA63CIPCON2.AMD